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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,608	04/05/2007	Frederik Henricus Wittkamp	0B-049910US	3431

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ST. JUDE MEDICAL, ATRIAL FIBRILLATION DIVISION
Legal Department
One St. Jude Medical Drive
St. Paul, MN 55117-9913

EXAMINER

SCOTT, AMANDA L

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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09/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,608	Applicant(s) WITTKAMPF ET AL.	
	Examiner AMANDA SCOTT	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/04/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22,27-29,31 and 38-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22,27-29,31 and 38-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of amendment filed 05/04/2009. Claims 14-22, 27-29, 31, and 38-48 are pending. An action on the merits is as follows.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cap shaped member the cup shaped member, and the convex inner portion of claim 45 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-22, 27-29, 31, and 38-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present application lists a unitary electrode in line 3 of claim 14, line 3 of claim 27 and line 2 of claim 38. There is no disclosure in the specification for a unitary electrode. The applicant claims that there are outlets running through the electrode tip which would render the tip not unitary in structure.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 44** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim element means for thermally insulating is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. Applicant does not state the means for thermally insulating in the specification. Any insulation would read on the claimed limitation

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

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(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 14-18, 22, 27-29, 31, and 38-48;** are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker (US 6,017,338).

9. **Regarding claim 14**, Brucker discloses a catheter comprising: an elongated body (22); a unitary electrode having at least one bore(view figure 9, the opening within tip 26 is a bore) formed through the electrode (column 5, line 67- column 6, line 2 and column 7, line 63- column 8, line 3; the tip 26 of the catheter acts as an electrode when in communication with the electrical connection 40), wherein the unitary electrode couples to and is disposed at a distal end portion of the elongate body (view figure 1); a conductive wire extending through said elongate body and electrically coupled to said

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unitary electrode (column 7, line 63- column 8, line 3); and an irrigation channel (28) extending through said elongate body and fluidly coupled (38) to a proximal portion of the at least one bore wherein said at least one bore includes at least one fluid outlet branch (58) coupling to a lateral side of the unitary electrode and said at least one fluid outlet branch (column 6, lines 16-32) includes one of a thermally insulating interior casing and a thermally poorly conductive material disposed within said at least one fluid outlet branch (tip is made of an insulating material, column 6, lines 33-49).

10. **Regarding claim 15**, Brucker discloses a catheter according to claim 14, wherein said at least one bore couples to a lateral exterior portion of the unitary electrode (view figure 9).

11. **Regarding claim 16**, Brucker discloses a catheter according to claim 14, wherein said irrigation channel has a longitudinal axis and said at least one branch comprises a series of outlet openings that guide a fluid supplied through said irrigation channel and said at least one bore (view figure 9).

12. **Regarding claim 17**, Brucker discloses a catheter according to claim 16, wherein the series of outlet openings are configured at an angle relative to the longitudinal axis, and wherein said angle comprises an angle of between about 30 degrees and about 90 degrees (view figure 9, the openings are about 90 degrees).

13. **Regarding claim 18**, Brucker discloses a catheter according to claim 16, wherein the series of outlet openings is provided with a thermally insulating unitary inner casing (the tip is made out of insulating material which would insulate the outlet openings; column 6, lines 33-49).

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14. **Regarding claim 22**, Brucker discloses the catheter according to claim 14, wherein said at least one bore terminate at an interface between said elongate body and said unitary electrode (28 can be considered to be a bore which terminates between the elongate body and the unitary electrode).

15. **Regarding claims 41 and 42**, Brucker discloses a catheter according to claim 14, further comprising a temperature sensor thermally coupled to said unitary electrode (column 7, lines 40-62, thermistor or thermocouple).

16. **Regarding claim 43**, Brucker discloses a catheter according to claim 14, further comprising low thermally conductive material casing disposed between the at least one bore and at least one fluid outlet branch and the unitary electrode (the tip is made of ceramic which insulates the fluid outlets and bore from the electrode attached to the tip).

17. **Regarding claim 44**, Brucker discloses a catheter according to claim 14, further comprising means for thermally insulating the interior of the at least one bore and the at least one fluid outlet branch from the unitary electrode (the tip is made of ceramic which insulates the fluid outlets and bore from the electrode attached to the tip).

18. **Regarding claims 45-47**, Brucker discloses the claimed catheter including providing a metallic member coupled to a thermally low conductive material (column 6, lines 3-15), wherein the unitary electrode is formed like one of a cap-shaped member and a cup-shaped member, each having a convex inner portion disposed adjacent the means for thermally insulating (view figures 2 and 3) and a temperature sensor (column 7, lines 40-62).

19. **Regarding claim 27**, Brucker discloses a catheter comprising: an elongated body (22); a unitary electrode (26 tip includes a electrode; column 4, lines 53-62) having longitudinal axis disposed at a first end of the elongate body(view figure 9) and having at least one outlet opening formed therethrough at an angle relative to the longitudinal axis (view figure 9); at least one electrically, conductive wire extending through said elongated body, said at least one electrically conductive wire coupled to said unitary electrode(column 7, line 63- column 8, line 3); an irrigation channel(28) extending through said elongated body and fluidly coupled(38) to the at least one outlet opening, said channel configured to deliver a fluid through said elongated body from a remote source of fluid and into said at least one passageway (column 6, lines 16-35); and one of a thermally insulative material and a thermally poorly conductive material disposed to insulate at least a portion of said at least one outlet opening (tip is made of an insulating material, column 6, lines 33-49).

20. **Regarding claim 28**, Brucker discloses a catheter according to claim 27, wherein said irrigation channel has a longitudinal axis and the at least one outlet opening is adapted to deliver said fluid to an outer surface of said elongated body in an outflow direction, and wherein said outflow direction comprises an angle relative to said longitudinal axis (view figure 9).

21. **Regarding claim 29**, Brucker discloses a catheter according to claim 28, wherein said at least one outlet opening comprises a plurality of outlet openings (view figure 9).

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22. **Regarding claim 31**, Brucker discloses a catheter according to claim 27, further comprising a temperature sensor coupled to the electrode at a distance from an interface formed between said elongated body and said unitary electrode (column 7, lines 40-62).

23. **Regarding claim 48**, Brucker discloses a catheter according to claim 27, further comprising a temperature sensor directly thermally coupled to the unitary electrode and spaced from the at least one outlet opening and the material (column 7, lines 40-62).

24. **Regarding claim 38**, Brucker discloses deploying a unitary electrode body coupled to a distal portion of an elongate flexible shaft into contact with a volume of a target tissue(abstract), wherein said unitary electrode body includes a longitudinal fluid passageway formed from a proximal end portion through to a less proximal surface portion and the fluid passageway couples to at least one outlet opening formed at an angle relative to the longitudinal fluid passageway (view figure 9, irrigation channel 28 and ports 60 and 54); measuring a temperature of said unitary electrode body with a temperature sensor coupled to the electrode body and spaced from the fluid passageway(column 7, lines 40-62); and dispensing fluid from a remote vessel(38) through an irrigation channel(28) within the elongate body fluidly coupled to said fluid passageway, wherein at least a portion of an interior surface of said at least one outlet opening comprises a thermally insulative material(tip is made of an insulating material, column 6, lines 33-49).

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25. **Regarding claim 39**, Brucker discloses a method according to claim 38, wherein the thermally insulative material comprises an electrically insulative material (column 6, lines 33-49; ceramic is electrically insulating).

26. **Regarding claim 40**, Brucker discloses a method according to claim 39, wherein one of the thermally insulative material and the electrically insulative material comprises preformed tubular member (the core is made of electrically insulating material and has preformed channels which is considered to be a preformed tubular member; column 6, lines 33-49).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. **Claims 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker (US 6,017,338) in view of Rydell (US 5,098,431).

31. **Regarding claim 19**, Brucker discloses the claimed catheter, but fails to explicitly disclose wherein the first end includes: a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core. However, Rydell discloses a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core (column 3, lines 12- 20). It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Brucker with the core and casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

32. **Regarding claim 20**, Brucker discloses the claimed catheter, wherein the core is made of plastic, ceramic, or glass (column 6, lines 3-15, and but fails to disclose wherein the casing is made of metal. However, Rydell discloses wherein the core is made of plastic, ceramic, or glass, and wherein the casing is made of metal (column 3, lines 12-20). It would have been obvious to one having ordinary skill in the art at the

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time of invention to combine the catheter taught by Brucker with the ceramic core and metal casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

33. **Regarding claim 21**, Brucker discloses the use of thermocouples and thermistors. Rydell discloses a casing that covers the core of an ablation catheter but fails to disclose a thermocouple attached to the casing. However it would have been obvious to one having ordinary skill in the art at the time the invention was made having Brucker and Rydell before them to place a temperature sensor on the casing of an ablation catheter. Doing so would enable the surrounding tissue's temperature to be monitored throughout the ablation procedure.

Response to Arguments

34. Applicant's arguments with respect to claims 14-22, 27-29, 31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SCOTT whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Thursday, 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/A. S./
Examiner, Art Unit 3739

/Linda C Dvorak/
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